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PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 CFR 1.53(b)(2).

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TITLE OF THE INVENTION (500 characters max)

METHOD AND APPARATUS FOR SIGNAL ENCODING EVOKED RESPONSES

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ENCLOSED APPLICATION PARTS (check all that apply)

Specification	Number of Pages	10
Claims	Number of Pages	2
Abstract	Number of Pages	1
Drawings	Number of Sheets	2
Other	Specify	

☒ Applicant Claims Small Entity Status

METHOD OF PAYMENT

A check or money order in the amount of:

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The Commissioner is hereby authorized to charge any additional fees or credit overpayment under 37 CFR 1.16 and 1.17, which may be required by this paper to Deposit Account 162201. *Duplicate copies of this sheet are enclosed.*

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No
☐ Yes, the name of the Government Agency and the Government Contract Number are:

Respectfully submitted,

Mark E. Books
Mark E. Books, Reg. No. 40,918

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SPECIFICATION

To All Whom It May Concern:

Be It Known That I, **Elvir Causevic**, a citizen of the United States, resident of the City of Ellisville in the State of Missouri, whose full post office address is 16315 Autumn View Terrace, Ellisville, Missouri 63011, have invented certain new and useful improvements in

METHOD AND APPARATUS FOR SIGNAL ENCODING EVOKED RESPONSES

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] Not Applicable.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

[0002] Not Applicable.

BACKGROUND OF THE INVENTION

[0003] The present invention is related generally to the introduction of auditory stimulus to a human ear, and to the detection of an evoked response signal and in particular, to the introduction of auditory stimulus to a human ear in a coded transmission sequence, and the detection of associated evoked response signals in a corresponding coded sequence whereby the effects of signal noise are reduced.

[0004] The measuring or monitoring of evoked or continuous bioelectric signals in a patient, such as an infant or other human patient who may be incapable of audiometric behavioral responses, is becoming an increasingly common method for initial patient screening or monitoring, and is used in auditory testing programs to identify hearing abnormalities, or in anesthesia and sedation monitoring to determine a patient's state, such as an awareness level.

[0005] In auditory screening, the functionality of the outer hair cells of the inner ear can be assessed with measurements of sounds in the external ear canal generated by the inner ear, called otoacoustic emissions (OAE), in response to clicks, called transient evoked OAE (TEOAE), or to two tones, called distortion product OAE (DPOAE).

[0006] As shown in Figure 1, below, a TEOAE is generated in response to a transient test signal, usually a sequence of square waves (click).

[0007] The level of these clicks is typically between 35 dB SPL and 90 dB SPL. In response to these test signals, a normal human ear generates a wide band signal up to 20 ms in duration after each click. As shown in Figure 1, the spectrum S_T of this response can be compared against the spectrum of ambient noise S_A to identify normal or abnormal hearing.

[0008] Similarly, as shown in Figure 2, below, a DPOAE is generated in response to the presentation of two simultaneous tonal signals, s_1 and s_2 with associated frequencies f_1 , and f_2 , with $f_2 > f_1$.

[0009] Typically, the ratio of the frequency of f_2 to f_1 is selected to be about 1.2, with amplitudes $|s_1| = 65$ dB SPL and $|s_2| = 55$ dB SPL in the ear canal. In response to these signals, a normal human ear generates, among others, a third tonal signal, the DPOAE at frequency $2f_1 - f_2$, which can be measured to identify normal or abnormal hearing.

[0010] Surface electrodes are utilized to detect bioelectric signals in a patient which are generated in response to an auditory stimulus. These bioelectric signals can be used both in auditory screening and in brain activity monitoring during anesthesia or sedation. An auditory evoked potential (AEP) is produced upon presentation of an auditory stimulus or series of stimuli, such as clicks or tone bursts. The AEP can be characterized by three components which refer to the latency of the response with respect to the stimulus; these are referred to as early, middle, and late components.

[0011] The early or short latency component of the AEP, the auditory brainstem response (ABR), occurs within the first 15ms after the presentation of the auditory stimulus and is widely used for clinical evaluation of hearing in infants and other individuals who are unable to effectively communicate whether a sound was detected.

In individuals with normal hearing, the ABR generates a characteristic neural waveform shown in Figure 3, below.

[0012] Auditory testing using the ABR typically involves a visual or statistical comparison of a tested individual's waveform to a normal template waveform. Like other evoked potentials, the ABR is recorded from surface electrodes on the scalp. However, the electrodes also record the background noise comprised of unwanted bio-potentials resulting from other neural activity, muscle activity, and unwanted non-physiological sources in the environment.

[0013] The middle component of the AEP, the auditory mid-latency response (AMLR), also referred to as the middle latency auditory evoked potential (MLAEP) occurs 15ms – 100ms after the presentation of the auditory stimulus, and is believed to reflect primary, non-cognitive, cortical processing of auditory stimuli. Lately, the AMLR, or MLAEP, has been of particular interest as a measure of depth of anesthesia.

[0014] It is known that the AMLR consists of positive and negative waves that are sensitive to sedatives and anesthetics. In general, increasing the level of sedation or anesthetic increases the latency of these waves, and simultaneously decreases the amplitudes. For monitoring purposes, changes in the AMLR waves are quantified as latency to peak, amplitude, and rate of change, and are sometimes combined in a single index.

[0015] Another component of the AEP, the auditory late response (ALR) occurs about 100ms after the auditory stimulus, and is believed to be especially sensitive to the level of sedation or anesthesia applied to a patient, and exhibits a distinct flattening of the waveform at a relatively light level of sedation or anesthesia, among other features.

[0016] It is further known that a 40Hz auditory signal can induce an enhanced "steady-state" AEP signal. Conventional signal averaging over a period of time is required to extract the AEP signal from background EEG signals, and adequate responses usually may be obtainable in about 30-40 seconds. The existence of an intact AEP is believed to be a highly specific indicator for the awake state of a patient, and gradual changes in the depth of sedation or anesthesia appear to be reflected by corresponding gradual changes in the AEP.

[0017] Several methods of encoding signals for transmission and reception are known which provide a resistance to signal noise. For transmitted and received signals there are two variables, frequency and time. Division by frequency, so that each pair of communicators is allocated part of the spectrum for all of the time, results in Frequency Division Multiple Access (FDMA). Division by time, so that each pair of communicators is allocated all (or at least a large part) of the spectrum for part of the time results in Time Division Multiple Access (TDMA). In Code Division Multiple Access (CDMA), every communicator will be allocated the entire spectrum all of the time. CDMA uses codes to identify connections. In this transmission technique, the frequency spectrum of a data-signal is spread using a code uncorrelated with that signal. As a result the bandwidth occupancy is much higher than required.

[0018] CDMA uses unique spreading codes to spread the baseband data before transmission. The signal is transmitted in a channel, which is below noise level. The receiver then uses a correlator to despread the wanted signal, which is passed through a narrow bandpass filter. Unwanted signals or noise will not be despread and will not pass through the filter. Codes take the form of a carefully designed one/zeros sequence

produced at a much higher rate than that of the baseband data. The rate of a spreading code is referred to as chip rate rather than bit rate.

[0019] Accordingly, it would be advantageous to provide a method and apparatus for utilizing the benefits of a coded signal transmission and corresponding coded response reception to enhance the performance of medical testing devices adapted to evoke and measure bio-potentials such as auditory evoked potentials and auditory brainstem response signals.

BRIEF SUMMARY OF THE INVENTION

[0020] Briefly stated, the present invention provides a method and apparatus for utilizing the benefits of coded signal transmissions and corresponding coded response reception to enhance the performance of medical testing devices adapted to evoke and measure bio-potentials such as auditory evoked potentials and auditory brainstem response signals. In a preferred embodiment, auditory stimuli, such as clicks, are presented to the ear of a human patient, in a predetermined coded sequence, resulting in the generation of corresponding coded bio-electric response signals in the human patient. These bio-electric signals from the patient are acquired and observed, and are processed according to the predetermined coded sequence in which the auditory stimuli were presented to the patient's ear in order to extract the desired auditory evoked potential signals or ABR signals.

[0021] In an alternate embodiment, the present invention provides a method and apparatus for utilizing the benefits of coded signal transmissions and corresponding coded response reception to enhance the performance of medical testing devices adapted to evoke and measure a variety of bio-potential response signals. Stimuli

selected to evoke a desired bio-potential response signal in a patient are presented to the patient in a predetermined coded sequence, resulting in the generation of corresponding coded bio-electric response signals in the patient. These bio-electric signals from the patient are acquired and observed, and are processed according to the predetermined coded sequence in which the stimuli were presented to the patient in order to extract the desired evoked potential signals for further processing.

[0022] The foregoing and other objects, features, and advantages of the invention as well as presently preferred embodiments thereof will become more apparent from the reading of the following description in connection with the accompanying drawings.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0023] In the accompanying drawings which form part of the specification:

[0024] Figure 1 is a graphical representation of a TEOAE response spectrum and an ambient noise spectrum;

[0025] Figure 2 is a graphical representation of a pair of test tones and a typical DPOAE response tone;

[0026] Figure 3 is a graphical representation of an auditory brainstem response to stimulus, compared with a no-stimulus signal;

[0027] Figure 4 is an illustration of the different types of spread-spectrum signal transmission and reception techniques;

[0028] Figure 5 is a flow-chart illustration of a sequence of stimuli encoded, and delivered to a patient, producing a sequence of correspondingly encoded evoked potential responses.

[0029] Corresponding reference numerals indicate corresponding parts throughout the several figures of the drawings.

DESCRIPTION OF THE PREFERRED EMBODIMENT

[0030] The following detailed description illustrates the invention by way of example and not by way of limitation. The description clearly enables one skilled in the art to make and use the invention, describes several embodiments, adaptations, variations, alternatives, and uses of the invention, including what is presently believed to be the best mode of carrying out the invention.

[0031] Turning to Figure 5, the steps of an embodiment of the present invention are illustrated for utilizing the benefits of encoded stimuli signal transmission to enhance the performance of medical testing devices adapted to evoke and measure bio-potentials such as auditory evoked potentials and auditory brainstem response signals.

[0032] Initially, a set of stimuli signals, such as audible clicks, are presented to a human patient at a high frequency in a predetermined encoded sequence. For example, as shown in Figure 3, a set of discrete and uniformly spaced stimulus signals are encoded by the addition of one or more stimulus signals spaced at varying intervals. The specific number and spacing of the additional signals is based on a predetermined mathematical encoding format, preferably selected from a set of encoding formats which are known to be highly resistant to signal noise and interference. The resulting encoded sequence of stimulus signals is then presented to the human patient in a conventional manner, such as with a speaker for auditory stimuli signals, or a light for visual stimuli signals.

[0033] The stimuli signals presented to the human patient are selected to evoke known bio-potential or auditory responses, which are detectable using conventional detection devices, such as electrodes or microphones. These evoked response signals are contained within the background noise naturally present in electrical potential or auditory signals from the human body, and hence must be filtered and processed prior to identification. Utilizing the predetermined encoded sequence of stimulus signals as part of the filtering and processing step facilitates identification of the presence and strength of the response signals, allowing for accurate reconstruction of the desired response signals and filtering of undesired signal noise.

[0034] The present invention can be embodied in the form of computer-implemented processes and apparatuses for practicing those processes. The present invention can also be embodied in the form of computer program code containing instructions embodied in tangible media, such as floppy diskettes, CD-ROMs, hard drives, or an other computer readable storage medium, wherein, when the computer program code is loaded into, and executed by, an electronic device such as a computer, micro-processor or logic circuit, the device becomes an apparatus for practicing the invention.

[0035] The present invention can also be embodied in the form of computer program code, for example, whether stored in a storage medium, loaded into and/or executed by a computer, or transmitted over some transmission medium, such as over electrical wiring or cabling, through fiber optics, or via electromagnetic radiation, wherein, when the computer program code is loaded into and executed by a computer, the computer becomes an apparatus for practicing the invention. When implemented in a general-

purpose microprocessor, the computer program code segments configure the microprocessor to create specific logic circuits.

[0036] In view of the above, it will be seen that the several objects of the invention are achieved and other advantageous results are obtained. As various changes could be made in the above constructions without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

CLAIMS:

1. A method for evoking and measuring bio-potential signals in a human patient, comprising:

providing a plurality of discrete stimulus signals to the human patient in a predetermined encoded sequence, each of said discrete stimulus signals selected to evoke one or more desired bio-potential response signals in the human patient;

acquiring bio-potential response signals from the human patient, said acquired bio-potential signals including signal noise; and

utilizing said predetermined encoded sequence to extract said desired bio-potential response signals from said acquired bio-potential signals.

2. The method of Claim 1 for evoking and measuring bio-potential signals wherein each of said discrete stimulus signals are auditory signals.

3. The method of Claim 1 for evoking and measuring bio-potential signals wherein said predetermined sequence is encoded in a redundant encoding format.

4. The method of Claim 1 for evoking and measuring bio-potential signals wherein said one or more desired bio-potential response signals are auditory evoked potential signals.

5. The method of Claim 4 for evoking and measuring bio-potential signals wherein said one or more desired bio-potential response signals are auditory brainstem response signals.

6. The method of Claim 1 for evoking and measuring bio-potential signals wherein said one or more desired bio-potential response signals are visual evoked potential signals.

7. The method of Claim 1 for evoking and measuring bio-potential signals wherein said one or more desired bio-potential response signals are tactile evoked potential signals.

ABSTRACT OF THE DISCLOSURE

A method and apparatus for utilizing the benefits of encoded signal transmission and reception to enhance the performance of medical testing devices adapted to evoke and measure bio-potentials such as auditory evoked potentials, and the auditory brainstem response signals in particular. Auditory stimuli, such as clicks, are presented to the ear of a human patient, in a predetermined encoded sequence, resulting in the generation of bio-electric response signals in the human patient. These bio-electric signals from the patient are acquired and observed, and are processed according to the predetermined encoded sequence in which the auditory stimuli were presented to the patient's ear in order to extract the desired auditory evoked potential signals or ABR signals.

METHOD AND APPARATUS FOR SIGNAL
ENCODING EVOKED RESPONSES
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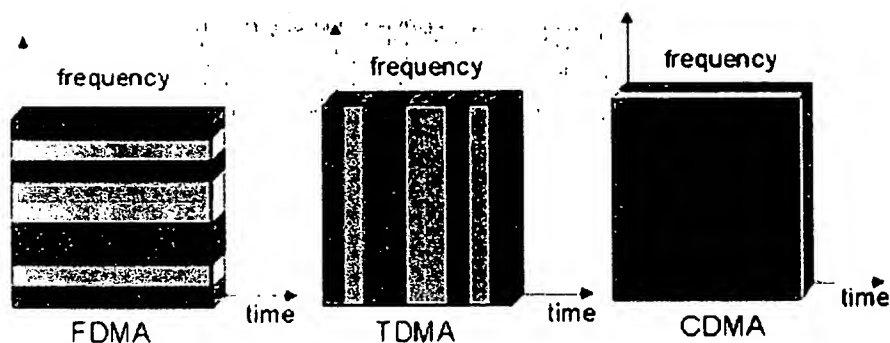


Figure 4
Prior Art

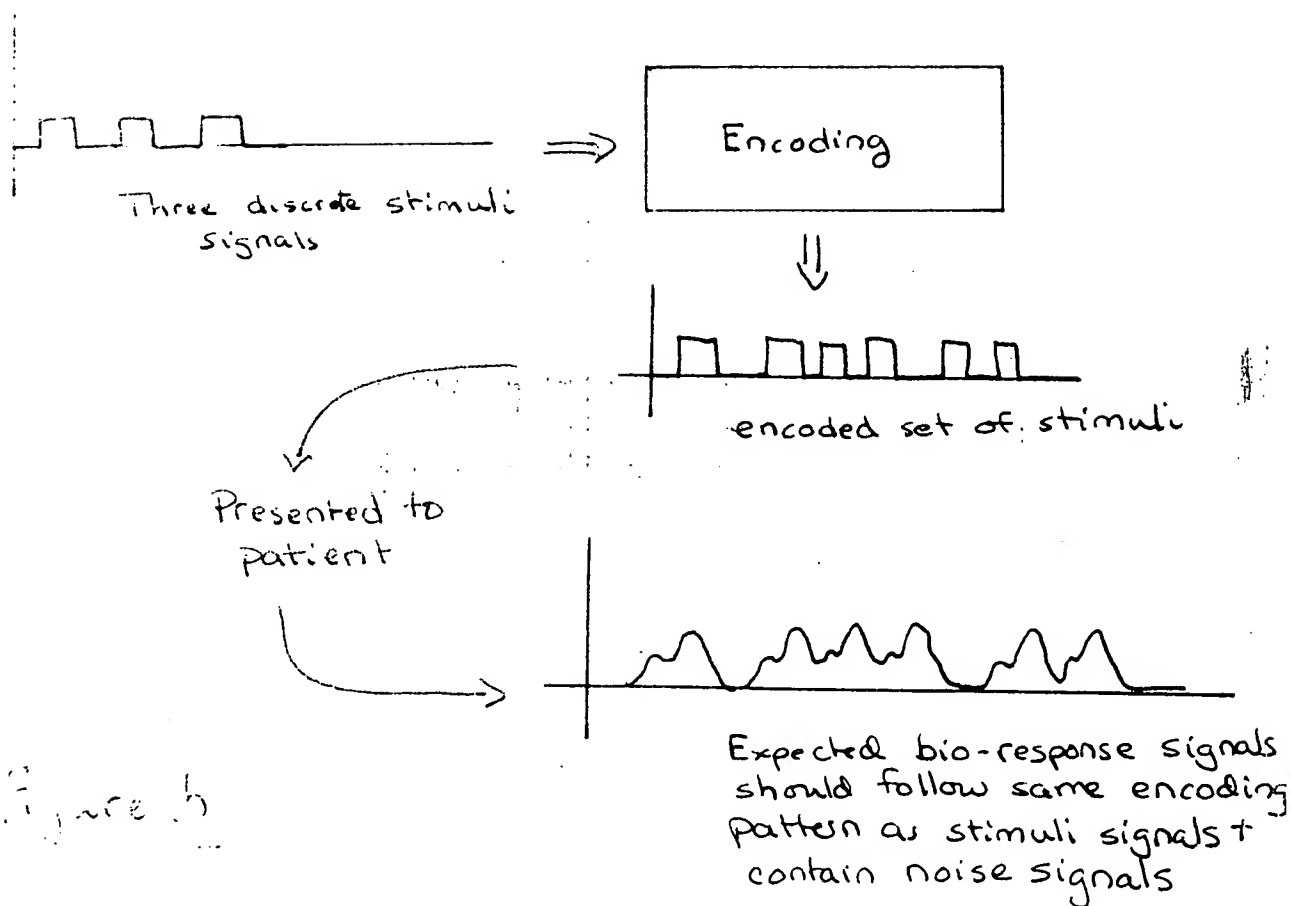


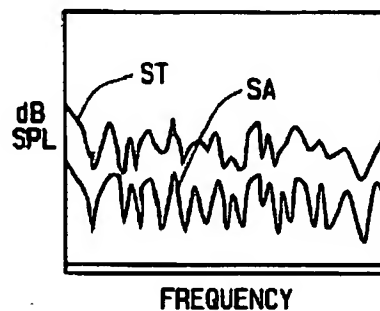
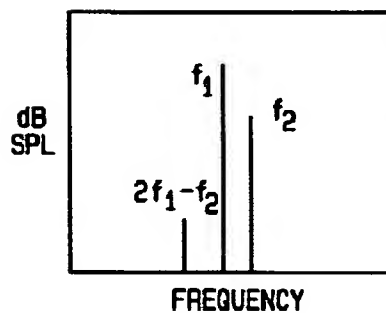
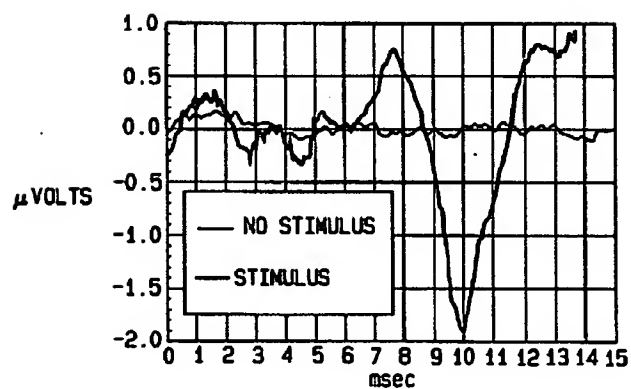
Figure 5

**METHOD AND APPARATUS FOR SIGNAL
ENCODING EVOKED RESPONSES**

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**Figure 1****Figure 2****Figure 3**